IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF ALABAMA
NORTHERN DIVISION

SUSIE WILLIAMS,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**Civil Action No.**
	)	
VIVA HEALTH INC., and RICKY CRAPP,	)	**2:07-cv-00321-WKW-TFM**
	)	
	)	
Defendants.	)	

DEFENDANT VIVA HEALTH INC.'S
RESPONSE TO PLAINTIFF'S MOTION TO REMAND

Defendant VIVA Health Inc. ("VIVA Health") hereby responds to Plaintiff's Motion to Remand ("Plaintiff's Motion") and Plaintiff's Memorandum of Law in support of Motion to Remand ("Plaintiff's Memorandum"). Because this Court has federal question subject matter jurisdiction over this action, Plaintiff's Motion is due to be denied.

I. INTRODUCTION AND SUMMARY

Plaintiff is a diabetic with about $8,000 in prescriptions each year. Plaintiff received marketing materials for VIVA Health's Medicare Advantage plan, which plainly described a prescription benefit limitation of $3,000 each year. Other than describing the $3,000 prescription benefit limitation in marketing materials, VIVA Health did not discourage Plaintiff from enrolling with VIVA Health.

Plaintiff sued VIVA Health in the Circuit Court of Bullock County, Alabama, seeking compensatory and punitive damages under numerous theories. Plaintiff's primary claim is that VIVA Health had a duty under Alabama law to discourage Plaintiff from enrolling in VIVA Health's Medicare Advantage plan because her diabetic condition indicated her need for future substantial prescriptions beyond the $3,000 prescription benefits limitation. In the Complaint, Plaintiff also sought compensation for expenses she would not have incurred but for enrolling with VIVA Health and alleged (1) that VIVA Health would not pay for syringes and was not going to pay for prescriptions in the future and (2) that she did not learn about the $3,000 prescription benefits limitation until after she enrolled with VIVA Health.

VIVA Health removed this action to federal court, because Plaintiff's Complaint challenged Medicare coverage decisions and because several of Plaintiff's claims had embedded federal issues giving rise to federal question jurisdiction. Plaintiff moved to remand this action to federal court, arguing that her state law claims are not preempted by federal law.

Plaintiff's primary claim is that VIVA Health had a duty under Alabama law to discourage Plaintiff from enrolling with VIVA Health, because her diabetic condition indicated a need for substantial future prescriptions beyond VIVA Health's $3,000 prescription benefit limitation. Under Medicare law, however,

VIVA Health was prohibited from discouraging Plaintiff from enrolling with VIVA Health based on her medical condition. Accordingly, any such duty under Alabama law would be preempted due to the conflict with federal law and due to the statutory express preemption by Medicare standards of any state law with respect to a Medicare Advantage plan.

In arguing against federal question jurisdiction, Plaintiff attempts to disavow two of the claims in the Complaint. One, Plaintiff asserts that she has no claim for Medicare benefits, despite the Complaint's allegations that VIVA Health would not pay for syringes and that her prescription coverage would run out and allegations that she seeks damages to compensate her for expenses she would not otherwise have incurred. Plaintiff also argues that she has not asserted a claim involving marketing materials, despite alleging that she did not learn about the $3,000 prescription benefit limitation from VIVA Health's marketing materials. Because the Complaint is the basis for removal, Plaintiff cannot avoid federal jurisdiction by disavowing a pled claim.

This Court has federal question jurisdiction on two grounds. First, Plaintiff's challenges of coverage decisions as to Medicare benefits are completely preempted. Second, Plaintiff asserted claims with federal law as a necessary element. As the United States Supreme Court's recent *Grable & Sons* decision makes clear, Plaintiff's claims based on the following allegations arise under

federal law: (1) not discouraging Plaintiff from enrolling with VIVA Health based on her medical condition, (2) not having adequate marketing materials to inform Plaintiff of the $3,000 prescription benefit limitation, or (3) challenging Medicare coverage decisions.

Plaintiff primarily alleges that Alabama law required VIVA Health to discourage Plaintiff from enrolling with VIVA Health, yet Medicare law prohibits such health screening. The existence of federal question jurisdiction based on a federal law's being an embedded element of Plaintiff's claim is most apparent from the conflict between this Medicare law and any such Alabama law and from the express Medicare preemption of any such Alabama law.

II. FACTUAL BACKGROUND

Plaintiff enrolled in VIVA Medicare Plus Select ("VIVA Medicare") and in the VIVA Health option of the Public Education Employees' Health Insurance Plan ("PEEHIP"). Affidavit of Latrina Hicks ("Hicks Aff.") ¶ 4 (Exhibit 2 to Defendant's Notice of Removal). For Medicare and PEEHIP eligible and enrolled retirees such as Plaintiff, VIVA Health is the Medicare Advantage organization (with VIVA Medicare's being the Medicare Advantage plan) that provides Medicare coverage, with PEEHIP providing secondary coverage. *Id.* ¶ 5

In the Complaint, Plaintiff alleged that "Plaintiff received a solicitation via U.S. Mail to enroll in VIVA prescription drug program," that Plaintiff contacted

Defendants and enrolled in VIVA Health's prescription drug program, and that only later "Plaintiff discovered through her local pharmacists that [VIVA Health] would only cover $3,000.00 of her prescription drugs in any calendar year and would not pay for syringes." Complaint ¶¶ 7-13.

As Exhibit B to Plaintiff's Memorandum [1] at 24-26 of 65, Plaintiff attaches "Defendant's first letter to Plaintiff." This letter describes, as the last bullet under "We offer the following benefits," the "Prescription Drug Benefit . . . up to $3000/year." *Id.* A copy of another mailing sent to Plaintiff before she enrolled with VIVA Health explains as follows: "Prescription benefits are limited to $3,000 per member per calendar year." Hick's Aff., Ex. B. This $3,000 prescription benefit was reviewed by an actuary and approved as creditable coverage as defined by the Centers for Medicare & Medicaid Services ("CMS"). *Id.* ¶ 8.

As relevant to VIVA Health's removal and Plaintiff's Motion, Plaintiff's Complaint alleged three state law counts: (a) Count I, "Negligent Procurement," alleging that Defendants did not ensure Plaintiff had the best medical coverage for her diabetic condition, (b) Count III, alleging wanton failure to know what Plaintiff's "Medical status was and what coverage she had" and changing her "coverage to a plan that will leave her without vital medicine necessary for her

[1] Plaintiff's Memorandum does not have normal page numbers. For clarity, the CM/ECF page numbers located at the top of the file-stamped Plaintiff's Memorandum and exhibits are cited herein. These CM/ECF page numbers are consecutive from 1 to 65.

survival," and (c) Count VI, alleging negligent hiring, training and supervision of Defendant Crapp in his job as a sales representative, "result[ing] in Plaintiff being enrolled in a health plan which was totally inadequate."

Plaintiff alleged that she "and her local Pharmacist have made every effort to correct the problems created by defendant's negligence and outrageous conduct to no avail." Complaint ¶ 18. Plaintiff has not, however, submitted any claim of any type to VIVA Health for prescriptions, syringes, or anything else that has not been paid. Hicks Aff. ¶ 7. The applicable Evidence of Coverage has a Grievance Procedure and a Complaint Procedure. Hicks Aff., Ex. A, pp. 52-73. Plaintiff has not submitted any grievance or complaint to VIVA Health. Hicks Aff. ¶ 7.

As averred in an affidavit filed by Plaintiff, a pharmacist made a number of telephone calls to VIVA Health, inquiring about the $3,000 limit on prescription benefits. Plaintiff's Memorandum, Ex. G at 47-65 of 65. This pharmacist "determined that the [VIVA Health] prescription program would not be sufficient to provide [Plaintiff] her needed insulin as there was a $3,000 cap on their drug program." *Id.*, Ex. G at 48 of 65. Plaintiff attaches what appear to be transcripts of telephone conversations between the pharmacist and unidentified individuals with VIVA Health. *Id.*, Ex. G at 47-65 of 65. Unless Plaintiff is asserting a claim for or at least intertwined with Medicare benefits, one cannot tell how or why this 18 page exhibit might relate to this action.

III. PLAINTIFF'S HEALTH SCREENING CLAIM

In Plaintiff's Memorandum at 10 of 65, Plaintiff asserts that "Plaintiff sued VIVA because they [sic] negligently screwed up her insurance." Plaintiff argues that VIVA Health should have "compar[ed] her present coverage to what she would be getting through VIVA" and "help[ed] the Plaintiff make an informed decision about changing insurance." Plaintiff's Memorandum at 8 of 65. The gist of Plaintiff's claim is that VIVA Health negligently failed to discourage Plaintiff from enrolling with VIVA Medicare, because the $3,000 limit on prescription benefits would be inappropriate for someone with her medical condition, which indicated her need for substantial future prescriptions. *Id.*; Complaint ¶¶ 13-17.

"Negligence is the failure to discharge or perform a legal duty owed to the other party." APJI Civil 28.00. Plaintiff asserts she has no claim based on VIVA Health's marketing materials, thus not contending that VIVA Health's marketing materials were inadequate. *See*, *infra*, pp. 18-19. Rather, Plaintiff is contending that VIVA Health had a legal duty, under Alabama law, to discourage Plaintiff from enrolling with VIVA Health (not just to inform her of the $3,000 prescription benefits limitation), because Plaintiff's medical condition indicated a need for substantial future prescriptions beyond what VIVA Health coverage provided.

Assuming *arguendo* that such a duty exists under Alabama law, any such duty would conflict with federal law. If a Medicare Advantage organization such

as VIVA Health did what Plaintiff advocates, federal law would consider such treatment of a Medicare beneficiary to be prohibited discrimination. *See* 42 C.F.R. § 422.110 (prohibiting any limiting of enrollment in a Medicare Advantage Plan "on the basis of any factor that is related to health status"). A Medicare Advantage organization is subject to Medicare "intermediate sanctions and civil money penalties" of 42 C.F.R. § 422.750 if the organization

> [e]ngages in any practice that could reasonably be expected to have the effect of denying or ***discouraging enrollment*** of individuals whose **medical condition or history indicates a need for substantial future medical services.**

42 C.F.R.§ 422.752(a)(4) (emphasis added). The Medicare Managed Care Manual, Chapter 15.20, similarly provides that CMS may impose intermediate sanctions on a Medicare Advantage organization for

> [e]ngaging in any practice that could reasonably be expected to have the effect of denying or ***discouraging enrollment*** of individuals whose **medical condition or history indicates a need for substantial future medical services.**

Accord Medicare Marketing Guidelines for Medicare Advantage Plans, p. 126 ("[P]lans are subject to sanction for engaging in any practice that may reasonably be expected to have the effect of denying or **discouraging enrollment** of individuals whose medical condition or history indicates a need for substantial future medical services (i.e., **health screening** or 'cherry picking')") (emphasis added); *id.*, p. 128 (explaining that contractors "cannot . . . [h]ealth screen when

distributing information to patients, as health screening is a prohibited marketing activity"). [2] The Medicare standards further explain as follows:

> An individual performing marketing may be in a position to enroll healthier beneficiaries into specific health plans (or "cherry pick"). "Cherry picking" healthier patients is problematic because it distorts the market and can be viewed as discriminatory. Therefore an individual performing marketing must not "cherry pick".

Id., p. 129. In essence, Plaintiff's Complaint seeks to hold VIVA Health liable for not health screening (by discouraging Plaintiff from enrolling with VIVA Health) and thus not cherry picking only healthier Medicare beneficiaries.

In summary, Plaintiff claims VIVA Health had a legal duty, under Alabama law, not only to tell Plaintiff about the $3,000 prescription benefit limitation, but also to discourage Plaintiff from enrolling with VIVA Health, because Plaintiff's medical condition indicated a need for substantial future prescriptions that the VIVA Health coverage did not provide. Any such duty under Alabama law would conflict with the Medicare standard prohibiting health screening.

IV. FEDERAL LAW PREEMPTS THE HEALTH SCREENING CLAIM

Plaintiff recognizes that a conflict between state and federal laws would result in the preemption of the state law. Plaintiff's Memorandum at 9 of 65. As to the conflict between the Medicare standard's prohibition against health

[2] Plaintiff accuses VIVA Health of "corporate greed." Plaintiff's Memorandum at 9 of 65. Yet, the profit maximizing strategy for a Medicare Advantage organization would be to discriminate based on health status by discouraging enrollment of individuals, like Plaintiff, whose medical conditions indicate a need for substantial future medical services.

screening and any duty under Alabama law to health screen, Plaintiff disputes that a conflict exists, but provides no legal or factual support or argument for her position. *Id.* at 8 of 65.

The federal preemption of any state law requiring health screening of Medicare participants does not rest on this conflict alone. The duty that Plaintiff contends exists under Alabama law would also be expressly preempted.

Plaintiff's arguments concerning federal preemption are difficult. First, Plaintiff argues as if VIVA Health had asserted ***field*** preemption, when VIVA Health has asserted ***conflict*** and ***express*** preemption. *Compare* Plaintiff's Memorandum at 7-11 of 65 (arguing against field preemption) *with* Notice of Removal ¶¶ 11-20 (asserting conflict and express preemption). Second, Plaintiff misinterprets the federal statute in question, which provides that Medicare standards expressly preempt state law with respect to Medicare Advantage plans.

The federal statute that Plaintiff misinterprets was part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") (Pub. L. No. 108-173, 117 Stat. 2066 (codified in scattered sections of 42 U.S.C.)). The MMA amended Medicare statutory express preemption. The current relevant statutory language is found in 42 U.S.C. § 1395w-26(b)(3):

> The standards established under this part shall supersede any state law or regulation (other than State licensing laws or State laws relating to

> plan solvency) with respect to [Medicare Advantage] plans which are offered by [Medicare Advantage] organizations under this part. [3]

Under "Avoiding duplicative State regulation," the relevant legislative history for the MMA explains as follows:

> The conference agreement clarifies that the [Medicare Advantage] program is a federal program operated under Federal rules. State laws do not and should not apply, with the exception of state licensing laws or state laws related to plan solvency. There has been some confusion in recent court cases.

H. Conf. Rep. 108-391 at 557, reprinted in 2003 U.S.C.C.A.N. 1808 at 1926.

In 2004, CMS promulgated 42 C.F.R. § 422.402, which almost repeats 42 U.S.C. § 1395w-26(b)(3). When commenting on "the reason for such broad preemption," CMS said "Congress intended that the [Medicare Advantage] program, a Federal program, operate under Federal rules." 69 Fed. Reg. 46904 (Aug. 3, 2004) (Attachment B hereto). CMS further explained the 2003 MMA amendment as follows:

> The presumption [before the 2003 MMA amendment] was that a state law was not preempted if it did not conflict with [a Medicare Advantage] requirement, and did not fall within one of the four categories where preemption was presumed . . . . [T]he MMA reversed this presumption and provided that state laws are *presumed to be preempted* unless they relate to licensure or solvency.

70 Fed. Reg. 4319 (2005) (Attachment C hereto) (emphasis added). Before the

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[3] The phrase "this part" is a reference to "Part C – Medicare + Choice Program," 42 U.S.C. §§ 1395w-21 to 1395w-28. As explained in Westlaw's Historical and Statutory Notes for 42 U.S.C. ¶¶ 1395w-21 (Attachment A hereto), after the 2003 MMA amendments, "any reference to 'Medicare + Choice' is deemed a reference to 'Medicare Advantage' or 'MA'."

2003 MMA amendment, 42 U.S.C. § 1395w-26(b)(3) had both specific and general preemption subsections. The specific preemption subsection "presumed" that four categories of state laws were "superseded" by Medicare standards: (i) "Benefit requirements," (ii) "Requirements relating to inclusion or treatment of providers," (iii) "Coverage determinations (including related appeals and grievances)," and (iv) "Requirements related to marketing materials . . . ." 42 U.S.C.A. § 1395w-26 (Westlaw's Historical and Statutory Notes) (Attachment D hereto). The general preemption subsection applied to all other state laws and superseded only state laws that were "inconsistent with" Medicare standards. *Id.*

The 2003 MMA amendment broadened Medicare preemption by removing any requirement that a state law be inconsistent with a Medicare standard and by presuming that any Medicare standard preempted all state law. Under the 2003 MMA amendment, where a Medicare standard exists, any state law "with respect to [Medicare Advantage] plans" is preempted. *See* 69 Fed. Reg. 46904 ("with the exceptions of State licensing laws or State laws related to plan solvency, ***State laws do not apply to [Medicare Advantage] plans***") (emphasis added).

In VIVA Health's Notice of Removal, VIVA Health explained the MMA express preemption of state law. Notice of Removal ¶¶ 13-15. In Plaintiff's Memorandum at 7 of 65, Plaintiff responded that VIVA Health "in an attempt to deceive this Court make[s] a rather specious argument regarding the [MMA's]

preemption of state law." *See also id.* at 10 of 65 ("Defendant VIVA removed this case from the state court relying on a very deceptive and specious argument to claim federal preemption").

Plaintiff's accusation appears to be based on a misunderstanding of the 2003 MMA amendment of Medicare preemption. Plaintiff incorrectly argues that "if [VIVA Health] had bothered to read the entire statute, they [sic] would have known that the intent was to preempt the states regarding rules that govern the qualifications of 'provider sponsored organizations' **and nothing more.**" Plaintiff's Memorandum at 8 of 65 (emphasis added). Correctly reading the entire statute, however, leads to an understanding that Plaintiff is mistaken.

Plaintiff attaches a copy of 42 U.S.C. § 1395w-25 and § 1395w-26 as Exhibit A to Plaintiff's Memorandum at 14-23 of 65. Only the provisions of 42 U.S.C. § 1395w-26(b) are relevant to general Medicare express preemption; the provisions of 42 U.S.C. § 1395w-25 and 42 U.S.C. § 1395w-26(a) are relevant only to limited preemption of state licensure and solvency standards. Under 42 U.S.C. § 1395w-25, the general rule is that Medicare Advantage organizations are licensed and regulated as to solvency under state law, with an exception for provider-sponsored organizations (a "provider" is a health care provider such as a hospital). Under 42 U.S.C. § 1395w-26(a), preemptive federal solvency standards are established for provider-sponsored organizations that are not state licensed.

The title of 42 U.S.C. § 1395w-26(b) is "Establishment of other standards." Under 42 U.S.C. § 1395w-26(b)(1), "[t]he Secretary shall establish by regulation other standards (not described in subsection (a) of this section) for [Medicare Advantage] plans consistent with, and to carry out this part." Consistent with subsection (b)'s title, subsection (b)(1)'s reference to "subsection (a) of this section" makes clear that the Medicare standards under 42 U.S.C. § 1395w-26(b) are those other than the federal solvency standards in 42 U.S.C. § 1395w-26(a) for provider-sponsored organizations. Therefore, reading all of 42 U.S.C. § 1395w-26 makes apparent that Medicare preemption is not limited to state laws "that govern the qualifications of 'provider sponsored organizations' and nothing more," Plaintiff's Memorandum at 8 of 65, as Plaintiff mistakenly contends.

In addition, before 2003, 42 U.S.C. § 1395w-26(b)(3) preempted state law with respect to benefit requirements, coverage determinations and marketing materials. In 2003, Congress intended to broaden Medicare preemption when it amended 42 U.S.C. § 1395w-26(b)(3), as explained, *supra*, pp. 10-12. Because the 2003 MMA amendment broadened Medicare preemption, Medicare preemption could not now be severely limited, as Plaintiff mistakenly contends.

When interpreting an express preemption clause, a court first focuses on the plain meaning of the statutory language, which provides the best evidence of congressional intent. *CSX Transp., Inc. v. Easterwood,* 507 U.S. 658, 664 (1993).

In discerning the scope of express preemption, a court may also look to the statutory framework and the structure and purposes of the statute as a whole. *Medtronic, Inc. v. Lohr,* 518 U.S. 470, 484-86 (1996). The language of the MMA, the statutory framework and structure, and the purposes of MMA preemption all point in one broad direction: Because a Medicare standard as to health screening is established, that standard supersedes any state law upon which Plaintiff's primary claim might be based.

For all of the above reasons, Medicare standards expressly preempt all state laws with respect to Medicare Advantage plans such as VIVA Medicare. Any Alabama law that might have given VIVA Health a duty to health screen Plaintiff is expressly preempted by the MMA and the Medicare standard prohibiting health screening. In other words, rather than having a duty under Alabama law to discourage Plaintiff from enrolling with VIVA Health, VIVA Health was prohibited by federal law from doing so.

V. PLAINTIFF ATTEMPTS TO DISAVOW TWO CLAIMS

In the Notice of Removal, VIVA Health identified two more claims in the Complaint that each create federal question jurisdiction: (1) Plaintiff challenged coverage decisions for Medicare benefits, without exhausting the federally mandated administrative remedies for Medicare Advantage plans; and (2) Plaintiff alleged that VIVA Health did not adequately inform her of the $3,000 limit on

prescription benefits in VIVA Health's marketing materials. Notice of Removal ¶ 23. Now, in Plaintiff's Memorandum, Plaintiff attempts to limit the scope of the Complaint, disavowing both the claim based on coverage of Medicare benefits and the claim based on VIVA Health's marketing materials.

A. Plaintiff Now Says No Claim for Medicare Benefits

In Plaintiff's Memorandum at 10 of 65, Plaintiff asserts that "Plaintiff has no claim for Medicare benefits that have been denied her. She, therefore, has no reason to go through an administrative hearing." In the Complaint ¶¶ 13 & 19, however, Plaintiff alleges that VIVA Health "would not pay for syringes" and that "Plaintiff seeks damages to compensate for expenses she otherwise would not have incurred . . . ." Plaintiff also alleges that "Plaintiff's prescription drug coverage will run out in April of 2007 . . . ." *Id.* ¶ 17. Therefore, Plaintiff's Complaint is inconsistent with the assertion in Plaintiff's Memorandum that she has no claim for Medicare benefits.

Furthermore, Plaintiff attaches as Exhibit G to Plaintiff's Memorandum what Plaintiff asserts are telephone conversations between VIVA Health and "Plaintiffs [sic] pharmacist when he tried to assist Plaintiff in getting this mess straightened out." Plaintiff's Memorandum at 10 of 65. If Plaintiff believed VIVA Health created "this mess," Plaintiff could have filed an administrative grievance and had an administrative hearing. *See Uhm v. Humana, Inc.*, 2006 WL 1587443,

at *3 (W.D. Wash. June 2, 2006) (explaining that "grievance procedures apply to any non-coverage-determination dispute"); Hicks Aff., Ex. A, pp. 52-73 (the available complaint procedure and grievance procedure).

The Medicare Act incorporates section 405(h) of the Social Security Act. 42 U.S.C. § 1395ii. Congress, in developing the elaborate remedial scheme for review of Medicare decisions, clearly intended that it would supersede other mechanisms for challenging coverage decisions. *Bodimetric Health Servs., Inc. v. Aetna Life & Cas.*, 903 F.2d 480, 487-88 (7th Cir. 1990). A plaintiff cannot avoid Medicare's exclusive mechanism for challenging coverage decisions "simply by styling its attack as a claim for collateral damages instead of a challenge to the underlying denial of benefits." *Id.* at 487.

Under *Heckler v. Ringer*, 466 U.S. 602, 614-15 (1984), any claim arising under the Medicare Act must be brought pursuant to § 405(g). Under § 405(h), § 405(g) is the sole avenue for judicial review of all claims arising under the Medicare Act. *Id.* If a claim is just "inextricably intertwined" with a claim for Medicare benefits, the claim thereby arises under the Medicare Act and thus is completely preempted. *Id.*

In the Complaint, Plaintiff alleged that VIVA Health denied claims for syringes and that VIVA Health made "a mess" as to claims for prescriptions and

syringes. Because the Complaint sought Medicare benefits or raised a dispute as to Medicare benefits, Plaintiff has pled a completely preempted claim.

Because Plaintiff failed to submit any administrative claim to VIVA Health, Hicks Aff. ¶ 7, it makes sense that Plaintiff would attempt to disavow the Complaint's allegations seeking expenses incurred due to VIVA Health's allegedly not covering Medicare benefits. In the Complaint, however, Plaintiff alleged that VIVA Health has not covered syringe claims and otherwise raised disputes as to benefits. Complaint ¶¶ 13 & 19. Plaintiff cannot deprive this Court of subject matter jurisdiction by disavowing a claim that is in the Complaint. *In re Wilson Indus.*, 886 F.2d 93, 95-96 (5th Cir. 1989).

B. Plaintiff Now Says No Marketing Materials Claim

In Plaintiff's Memorandum at 8 of 65, Plaintiff asserts that "Plaintiff has made no claim that involves Defendant's marketing materials." In the Complaint ¶ 13, however, Plaintiff alleged that, after enrolling, "Plaintiff discovered through her local Pharmacists that [VIVA Health] would only cover $3,000 of her prescription drugs in any calendar year and would not pay for syringes."

Because the Complaint's allegations are inconsistent with the VIVA Health marketing materials, it makes sense that Plaintiff would attempt to disavow the Complaint's allegations as to marketing materials. *Compare* Complaint ¶ 13 *with* Plaintiff's Memorandum, Exhibit B at 24-26 of 65 ("Defendant's first letter to

Plaintiff," with the following: "Prescription Drug Benefit . . . up to $3000/year") *and* Hick's Aff. Ex. B (a copy of another marketing letter sent to Plaintiff before she enrolled with VIVA Health explaining as follows: "Prescription benefits are limited to $3,000 per member per calendar year.").

Federal regulations for "approval of marketing materials" preempt Plaintiff's claims to the extent they relate to VIVA Medicare's marketing materials. *See* 42 C.F.R. § 423.50 (2005) ("Approval of marketing materials"); *Uhm*, 2006 WL 1587443, at *2 (holding that state law tort claims "are preempted to the extent that they rely on [a Medicare Advantage organization's] marketing materials"). Accordingly, to the extent that Plaintiff's claims rely on the adequacy of VIVA Health's marketing materials, Plaintiff's claims are preempted.

By disavowing any claim that involves VIVA Health's marketing materials, Plaintiff is admitting that those marketing materials were adequate. As discussed above, the marketing materials explain the $3,000 prescription benefit. Plaintiff cannot, however, deprive this Court of subject matter jurisdiction by disavowing this claim pled in the Complaint. *In re Wilson Industries*, 886 F.2d at 95-96.

VI. PLAINTIFF'S ARGUMENT AS TO FEDERAL EMPLOYEES

In Plaintiff's Memorandum at 9 of 65, Plaintiff argues that "For the sake of demonstrating how absurd Defendants' [sic] arguments are [sic] Plaintiff would point out that pursuant to 42 U.S.C. § 1395, this Court is prohibited from

interfering in this case." Plaintiff then quotes 42 U.S.C. § 1395 and states that "[b]ased on the language [in 42 U.S.C. § 1395], no one in the federal government's employ [Plaintiff even means no federal judge?] can tell Defendant how to administer its business." *Id.* Plaintiff's argument is not correct.

First, 42 U.S.C. § 1395 is inapposite. It provides that Medicare does not "authorize any federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided." 42 U.S.C. § 1395. VIVA Health, however, is not a physician, hospital or other medical provider practicing medicine or providing medical services. Instead, VIVA Health is a health maintenance organization ("HMO") organized under Alabama Code, Title 27 "Insurance," Chapter 21A "Health Maintenance Organizations," §§ 27-21A-1 to 27-21A-32. Under Alabama law, an HMO arranges for medical services to be provided, but itself is in the "business of insurance." Ala. Code § 27-21A-15(a); *see also* Ala. Code 27-21A-23(c) (an HMO "shall not be deemed to be practicing medicine"). Because VIVA Health is not practicing medicine or providing medical services, 42 U.S.C. § 1395 does not apply in this action.

Second, CMS publishes a big Medicare Managed Care Manual. *See* http://www.cms.hhs.gov/Manuals/IOM/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=1&sortOrder=ascending&itemID=CMS019326 (an electronic

copy of the manual). This manual has twenty chapters and is several inches thick when printed out. It gives detail after detail of CMS's telling VIVA Health and other Medicare Advantage organizations how to run their businesses. If any federal law provides that "no one in the federal government's employ can tell [VIVA Health] how to administer its business," as argued by Plaintiff, CMS violates that law by publishing the Medicare Managed Care Manual.

VII. THIS COURT HAS FEDERAL QUESTION JURISDICTION

Federal question jurisdiction exists where a plaintiff's suit "arises under" the "Constitution, treaties or laws of the United States." 28 U.S.C. § 1331. In general, a case "arises under" federal law if the plaintiff pleads a cause of action created by federal law ***or*** if a substantial disputed area of federal law is a necessary element of a state law claim. *Franchise Tax Bd. v. Constr. Laborers Vacation Trust,* 463 U.S. 1, 9-10, 13 (1983). As explained in VIVA Health's Notice of Removal ¶ 12, Plaintiff's claims arise under federal law both because (a) based on complete preemption of state law, Plaintiff has pled a claim under federal law, and (b) Plaintiff has pled one, two or three claims for which a substantial disputed area of federal law is a necessary or "embedded" element.

A. Any Claim as to Medicare Benefits is Completely Preempted

Plaintiff does not argue that a state law claim as to Medicare benefits is not completely preempted. *Cf. Heckler*, 466 U.S. at 614-15 (any claim as to Medicare

benefits must be brought pursuant to § 405(g)); *Bodimetric Health Services, Inc.*, 903 F.2d at 487-88 (Medicare's exclusive mechanism to challenge coverage decisions is § 405(g)). Instead, Plaintiff argues she "has no claim for Medicare benefits that have been denied her." Plaintiff's Memorandum at 10 of 65.

In Plaintiff's Complaint, however, Plaintiff alleges that VIVA Health "would not pay for syringes" and that "Plaintiff seeks damages to compensate for expenses she otherwise would not have incurred . . . ." Complaint ¶¶ 13 & 19. Plaintiff also alleges that "Plaintiff's prescription drug coverage will run out in April of 2007 . . . ." *Id.* ¶ 17. Until Plaintiff amends the Complaint to drop the coverage decision challenges, Plaintiff has alleged completely preempted claims.

B. Plaintiff's Claims with Federal Law as a Necessary Element

In addition to complete preemption, a state law claim for which a substantial disputed area of federal law is a necessary element gives rise to federal question jurisdiction. In 2005, the Supreme Court clarified that a claim need not be brought under federal law for there to be valid federal question jurisdiction. *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 317-18 (2005); *see McCready v. White*, 417 F.3d 700, 702-03 (7th Cir. 2005) (noting that *Grable & Sons* put the "kibosh" on the possibility that a federal cause of action was necessary to establish federal question jurisdiction); *In re Pharm. Indus. Average Wholesale Price Litig.*, 457 F. Supp. 2d 77, 80 (D. Mass. 2006) (following *Grable*

& Sons to deny a motion to remand; recognizing that before *Grable & Sons* the same judge had granted a similar motion to remand in an identical action).

In Plaintiff's Memorandum at 11 of 65, Plaintiff discusses *Burke v. Humana Insurance Co.*, 1995 WL 841678 (M.D. Ala), and *Grace v. Interstate Life & Accident Insurance Co.*, 916 F. Supp. 1185 (M.D. Ala. 1996). To the extent *Burke* or *Grace* might hold that a federal cause of action is necessary to establish federal question jurisdiction, *Grable & Sons* makes clear that *Burke* and *Grace* would not be good law. In any event, both *Burke* and *Grace* are distinguishable from this action, because neither held that a claim based on a state law that conflicts with a Medicare standard or that was expressly preempted by a Medicare standard could not be removed based on an embedded federal issue.

Under *Grable & Sons*, the dispositive question for federal question jurisdiction based on an embedded federal issue is as follows: "does a state-law claim necessarily raise a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities." 545 U.S. at 314. In *Grable & Sons*, the Supreme Court guided lower courts to engage in a "contextual inquiry" that examines "the importance of having a federal forum for the issue, and the consistency of such a forum with Congress's intended division of labor between state and federal courts." *Id.* at 318-19.

Plaintiff's claims present three embedded federal issues, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities: (a) Can VIVA Health be liable to Plaintiff under state law for not discouraging her from enrolling with VIVA Health, when such health screening is prohibited by federal law? (b) Can VIVA Health be liable to Plaintiff under state law for allegedly insufficient marketing materials, when marketing materials are to comply with federal law? And, (c) can Plaintiff, by bringing state law claims, avoid the federally mandated administrative remedies for Medicare Advantage plans that are Medicare's exclusive mechanism for challenging coverage decisions? Each of these three embedded federal issues presents a substantial and disputed federal issue and is an element of a claim pled by Plaintiff. A federal forum is important for all and each of these issues, as shown by Congress's express preemption of state laws for these issues, as explained above.

The strength of the federal interest and the lack of any possible state interest (*i.e.*, any state law duty is expressly preempted) are most stark for Plaintiff's health screening claim. This Court, as a federal forum, may entertain this health screening claim without disturbing any congressionally approved balance of federal and state judicial responsibilities. Indeed, Congress's broad MMA preemption shows that the congressionally approved balance of federal and state

judicial responsibilities impels this Court to provide a federal forum to interpret the federal rules for this federal program and thus promote and protect the preemptive federal interest in a uniform Medicare program from any conflicting state laws that Plaintiff is attempting to rely upon.

VIII. CONCLUSION

Because Plaintiff has pled a claim under federal law for Medicare benefits or because Plaintiff has pled one, two or three claims for which a substantial disputed area of federal law is a necessary element, this action was properly removed under 28 U.S.C. § 1331 and Plaintiff's Motion should be denied.

/s/ James S. Christie, Jr.
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Attorneys for Defendant
VIVA Health, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on May 21, 2007, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the following:

L. Cooper Rutland, Jr.
Rutland Law Firm, L.L.C.
208 North Prairie Street
Post Office Box 551
Union Springs, Alabama 36089
334-738-4770
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and hereby certify that I have mailed by United States Postal Service the document to the following non-CM/ECF participants:

None

/s/ James S. Christie, Jr.
One of the Attorneys for
Defendant VIVA Health, Inc.

Attachment A

plans) offered in different areas and the election process provided under this section." at the end.

Subsec. (e)(4). Pub.L. 108–173, § 102(a)(1)(B), struck out "2005" and inserted "2006" each place it appeared.

Subsec. (e)(5)(A)(i). Pub.L. 108–173, § 233(d)(1), added "or" at the end.

Subsec. (e)(5)(A)(ii). Pub.L. 108–173, § 233(d)(2), struck out ", or" at the end, and inserted a semicolon.

Subsec. (e)(5)(A)(iii). Pub.L. 108–173, § 233(d)(3), struck out cl. (iii), which read: the month of November 1998;"

Subsec. (f)(1). Pub.L. 108–173, § 222(*l*)(3)(E), struck out "subsection (e)(1)(A) of this section" and inserted "subsection (e)(1) of this section".

Subsec. (f)(3). Pub.L. 108–173, § 102(a)(5), inserted ", other than the period described in clause (iii) of such subsection" following "subsection (e)(3)(B) of this section".

Subsec. (i)(1). Pub.L. 108–173, § 237(b)(2)(A)(i), inserted "1395w–23(a)(4)," after "Subject to sections 1395w–22(a)(5),".

Subsec. (i)(2). Pub.L. 108–173, § 221(d)(5), inserted "1395w–27a(h)," after "1395w–27(f)(2),".

Pub.L. 108–173, § 237(b)(2)(A)(ii), inserted "1395w–23(a)(4)," after "Subject to sections".

Effective and Applicability Provisions

2003 Acts. Pub.L. 108–173, Title I, § 102(c)(2), Dec. 8, 2003, 117 Stat. 2154, provided that: "The amendments made by this subsection [amending subsec. (a) of this section] shall apply on and after January 1, 2006."

Pub.L.108–173, Title II, § 223(a), Dec. 8, 2003, 117 Stat. 2207, provided that: "The amendments made by this subtitle [enacting 42 U.S.C.A. § 1395w–27a, amending this section, 42 U.S.C.A. §§ 1395r, 1395s, 1395w, 1395w–22, 1395w–23, 1395w–24, 1395w–27, and 1395w–28, and enacting provisions set out as a note under this section] shall apply with respect to plan years beginning on or after January 1, 2006."

Pub.L. 108–173, Title II, § 231(f)(1), Dec. 8, 2003, 117 Stat. 2208, provided that: "The amendments made by subsections (a), (b), and (c) [amending subsec. (a)(2)(A)(ii) of this section and 42 U.S.C.A. § 1395w–28] shall take effect upon the date of the enactment of this Act [Dec. 8, 2003]."

Amendments by Pub.L. 108–173, § 237, apply to services provided on or after Jan. 1, 2006, and contract years beginning on or after such date, see Pub.L. 108–173, § 237(e), set out as a note under 42 U.S.C.A. § 1320a–7b.

Implementation of Medicare Advantage Program

Pub.L. 108–173, Title II, § 201, Dec. 8, 2003, 117 Stat. 2176, provided that:

"**(a) In general.**—There is hereby established the Medicare Advantage program. The Medicare Advantage program shall consist of the program under part C of title XVIII of the Social Security Act (as amended by this Act) [the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub.L. 108–173, Dec. 8, 2003, 117 Stat. 2066, which amended this part; see Tables for complete classification].

"**(b) References.**—Subject to subsection (c) [of this note], any reference to the program under part C of title XVIII of the Social Security Act [this part] shall be deemed a reference to the Medicare Advantage program and, with respect to such part, any reference to 'Medicare + Choice' is deemed a reference to 'Medicare Advantage' and 'MA'.

"**(c) Transition.**—In order to provide for an orderly transition and avoid beneficiary and provider confusion, the Secretary shall provide for an appropriate transition in the use of the terms 'Medicare + Choice' and 'Medicare Advantage' (or 'MA') in reference to the program under part C of title XVIII of the Social Security Act [this part]. Such transition shall be fully completed for all materials for plan years beginning not later than January 1, 2006. Before the completion of such transition, any reference to 'Medicare Advantage' or 'MA' shall be deemed to include a reference to 'Medicare + Choice'."

Report on Impact of Increased Financial Assistance to Medicare Advantage Plans

Pub.L. 108–173, Title II, § 211(g), Dec. 8, 2003, 117 Stat. 2178, provided that: "Not later than July 1, 2006, the Secretary shall submit to Congress a report that describes the impact of additional financing provided under this Act [the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub.L. 108–173, Dec. 8, 2003, 117 Stat. 2066; see Tables for complete classification] and other Acts (including the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 [Pub.L. 106–113, Div. B, § 1000(a)(6), Nov. 29, 1999, 113 Stat. 1536, 1501A–321; see Tables for classification] and BIPA [the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Pub.L. 106–554, § 1(a)(6), Dec. 21, 2000, 114 Stat. 2763, 2763A–463; see Tables for classification]) on the availability of Medicare Advantage plans in different areas and its impact on lowering premiums and increasing benefits under such plans."

MedPAC Study and Report on Clarification of Authority Regarding Disapproval of Unreasonable Beneficiary Cost-Sharing

Pub.L. 108–173, Title II, § 211(h), Dec. 8, 2003, 117 Stat. 2179, provided that:

"**(1) Study.**—The Medicare Payment Advisory Commission, in consultation with beneficiaries, consumer groups, employers, and organizations offering plans under part C of title XVIII of the Social Security Act [this part], shall conduct a study to determine the extent to which the cost-sharing structures under such plans affect access to covered services or select enrollees based on the health status of eligible individuals described in section 1851(a)(3) of the Social Security Act (42 U.S.C. 1395w–21(a)(3) [subsec. (a)(3) of this section]).

"**(2) Report.**—Not later than December 31, 2004, the Commission shall submit a report to Congress on the study conducted under paragraph (1) together with recommendations for such legislation and administrative actions as the Commission considers appropriate."

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three other types of facilities are now included: rehabilitation hospitals, distinct part rehabilitation units, and long-term care hospitals. These changes are reflected in proposed § 422.318, which otherwise retains existing language from subpart F applicable only to subsection (d) hospitals.

10. Special Rules for Hospice Care (§ 422.320)

Proposed § 422.320 revises the existing MA special rules for hospice care to reflect the new bidding and payment methodology in sections 1853 and 1854 of the Act, and the creation of a prescription drug benefit under Part D. Previously, no payment was made to an MA organization on behalf of a Medicare enrollee who had elected hospice care under § 418.24 except for the portion of the payment applicable to the additional benefits. Now the MA organization will be paid the portion of the payment attributable to the beneficiary rebate for the MA plan plus the amount of the subsidies related to basic prescription drug coverage for plans that offer prescription drug coverage.

Note that for PACE organizations, PACE enrollees must elect either their PACE plan or the hospice benefit as their provider of Medicare services. An enrollee who elects to enroll in hospice is thereby disenrolled from the PACE benefit. However, PACE plans do provide a service similar to hospice known as "end-of-life-care."

11. Source of Payment and Effect of MA Plan Election on Payment (§ 422.322)

With the exception of a new provision addressing payments for Part D benefits, proposed § 422.322 is identical to § 422.268 in subpart F of the current MA regulations at § 422.268. Section 422.322(a)(2) has been added to reflect the creation of subsidized prescription drug coverage under Part D. As required by section 1853(f) of the Act, subsidy payments to MA–PD organizations for basic drug coverage under this title are included in the payments described in § 422.322(a)(2) (which are made from the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund).

12. Payments to MA Organizations for Graduate Medical Education Costs (§ 422.324)

These provisions are identical to the current MA provisions in subpart F at § 422.270, and require us to make payments to MA organizations for Direct Graduate Medical Education costs that MA organizations incur in dealings with non-hospital provider settings, under specified conditions.

Subpart I—Organization Compliance With State Law and Preemption by Federal Law

(If you choose to comment on issues in this section, please include the caption "Subpart I—Organization Compliance with State Law and Preemption by Federal Law" at the beginning of your comments.)

The MMA amended section 1856(b)(3) of the Act relating to Federal preemption of State law. Before this amendment, section 1856(b)(3) of the Act provided for two types of preemption, general and specific. Section 1856(b)(3)(A) of the Act provided that State laws that were inconsistent with M+C rules were preempted. Section 1856(b)(3)(B) of the Act provided that, even if a State law did not conflict with an M+C standard, it was preempted if it addressed one of four specified areas (benefit requirements, including cost-sharing rules; requirements relating to the inclusion or treatment of providers; requirements concerning coverage determinations and related appeals and grievance processes; and requirements relating to marketing materials and summaries and schedules of benefits concerning M+C plans).

Thus, the presumption was that a State law was *not* preempted if it did not conflict with an M+C requirement, and did not fall into one of the four specified categories. MMA reversed this presumption, providing that State laws are presumed to be preempted unless they fall into two specified categories. Specifically, section 1856(b)(3) of the Act now states that "the standards established under this section shall supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency)." The reason for such broad preemption authority is that the Congress intended that the MA program, as a Federal program, operate under Federal rules. There has been some confusion in recent court cases with respect to the preemption of State laws. Therefore, this broad preemption would apply prospectively, that is, it would not affect previous and ongoing litigation related to preemption of State laws. Furthermore, we believe the Congress broadened this authority to facilitate the operation of regional PPOs, which may have service areas that cross State lines.

We note that the Conference Report makes it clear that the Congress intended to broaden the scope of preemption through this change. Thus, we believe that the exception for State laws that relate to "State licensing" must be limited to State requirements for becoming State licensed, and would not extend to any requirement that the State might impose on licensed health plans that—absent Federal preemption—must be met as a condition for keeping a State license.

If a State requirement could be considered to relate to State licensing simply because the State could revoke a health plan's license for a failure to meet the requirement, this would mean that States could impose virtually any requirement they wished to impose without the requirement being preempted. This would extend even to State laws that were specifically preempted under the pre-MMA version of section 1856(b)(3) of the Act, such as benefit requirements, rules regarding the inclusion and treatment of providers, and rules regarding coverage decisions and related grievances and appeals. Because we believe that it is clear that the Congress intended to broaden the scope of Federal preemption, not to narrow it, we also believe that the exception for laws relating to State licensing must be limited to requirements for becoming State licensed (such as filing articles of incorporation with the appropriate State agency, or satisfying State governance requirements), and not extended to rules that apply to State licensed health plans.

Upon review of this regulation, we do not believe that the language in existing paragraph (c) of § 422.402 is necessary. Section 422.402(c) currently states that nothing in this section may be construed to affect or modify "any other law or regulation that imposes or preempts a specific State authority." We do not believe that this paragraph has any real effect, since the real issue would be whether the preemption in section 1856(b)(3) of the Act is controlling on the matter. This analysis would be unaffected by language in a regulation implementing section 1856(b)(3) of the Act. We therefore are proposing to remove the current § 422.402(c).

We therefore propose to revise § 422.402 to clearly state that the MA standards supersede State law and regulation with the exception of licensing laws and laws relating to plan solvency. Accordingly, with the exceptions of State licensing laws or State laws related to plan solvency, State laws do not apply to MA plans offered by MA organizations.

MMA also amended section 1854(g) of the Act, which prohibits States from imposing taxes on premiums paid to MA Organizations by us. Section 232 of

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required to comply with the solvency standards established by us. In the event the State ultimately denied the application, we stated that we could extend the waiver through the contract year as we deemed appropriate to provide for transition.

In the final rule we have clarified, with the addition the distinctions between the temporary waiver (for regional plans) and the waiver for entities seeking to offer a plan in a single State, the timeline for processing the application for the waiver and the length of the waiver itself. Thus in new § 423.415(c) we clarify that Secretary will determine the time period appropriate for the processing of the application and in new § 423.415(d), we repeat the policy of the proposed rule that in no case will the temporary waiver extend beyond the end of the calendar year.

4. Solvency Standards for Non-Licensed Entities (§ 423.420)

In proposed § 423.420, we specified that sponsors that have been granted a waiver by us must maintain reasonable financial solvency and capital adequacy.

Solvency standards have been developed after statutorily required consultation with the National Association of Insurance Commissioners. These standards are undergoing internal CMS review. We anticipate that these standards, which are required to be published by January 1, 2005 will be published on the CMS website in the near future in conjunction with the initial application forms for PDP organizations. These solvency standards will include such items as required minimum net worth and liquidity requirements as well as reporting requirements for future PDPs who have received waiver of State licensure. We are adopting the policy we proposed for reasonable financial solvency and capital adequacy in this final rule.

5. Preemption of State Laws and Prohibition of Premium Taxes (§ 423.440)

In the August 4, 2004 proposed rule, we stated that we would implement section 1860D–12(g) of the Act at proposed § 423.440(a), by specifying that to the extent there are Federal standards, those standards supersede any State Law.

We proposed that for purposes of Part D, with the exceptions of State licensing laws or State laws related to plan solvency, State laws would not apply to prescription drug plans and PDP sponsors.

The proposed rule for the Medicare Advantage program also discussed preemption of State laws, and because Part D and Part C incorporate the same preemption laws at section 1856(b)(3) of the Act, we believe it is necessary to summarize those discussions in this final rule.

In the Medicare Advantage proposed rule, we noted that prior to enactment of the MMA, section 1856(b)(3) of the Act provided for two types of preemption: general and specific. The presumption was that a State law was not preempted if it did not conflict with an M+C requirement, and did not fall into one of the four specified categories where preemption was presumed. (These four categories were: benefit requirements, including cost-sharing rules; requirements relating to the inclusion or treatment of providers; requirements concerning coverage determinations and related appeals and grievance processes; and requirements relating to marketing materials and summaries and schedules of benefits concerning M+C plans.)

We concluded that the MMA reversed this presumption and provided that State laws are presumed to be preempted unless they relate to licensure or solvency. We also referenced the Congress' intent that the MA program, as a Federal program, operate under Federal rules, and referred to the Conference Report of the MMA as making clear the Congress' intent to broaden the scope of preemption through its change to section 1856(b)(3) of the Act. See 69 FR 46866, 46904. We believe that because the Congress incorporated the same preemption standard into the Part D program, and because the Congress required the preemption rules to apply consistently in Parts C and D, this same reasoning would apply to Part D.

In addition, in the proposed rule for Part D, we stated that although the Congress included broad preemption rules in section 1856(b)(3) of the Act, we did not believe that the Congress intended for each and every State requirement applying to PDP sponsors to become null and void. Specifically, we stated:

> In areas where we have neither the expertise nor the authority to regulate, we do not believe that State laws would be superseded or preempted. For example, State environmental laws, laws governing private contracting relationships, tort law, labor law, civil rights laws, and similar areas of law would, we believe, continue in effect and PDP sponsors in such States would continue to be subject to such State laws. Rather, our Federal standards would merely preempt the State laws in the areas where the Congress intended us to regulate—such as the rules governing pharmacy access, formulary requirements for prescription drug plans, and marketing standards governing the information disseminated to beneficiaries by PDP sponsors. We believe this interpretation of our preemption authority is in keeping with principles of Federalism, and Executive Order 13132 on Federalism, which requires us to construe preemption statutes narrowly. (69 FR 46696.)

We also recognized that while the Congress specifically stated that State licensure and solvency laws would not be preempted, this did not mean that States could condition licensure on a sponsor meeting requirements unrelated to what we would consider licensure requirements. We also addressed this issue in the Medicare Advantage proposed rule, explaining:

> We believe that the exception for State laws that relate to "State licensing" must be limited to State requirements for becoming State licensed, and would not extend to any requirement that the State might impose on licensed health plans that-absent Federal preemption-must be met as a condition for keeping a State license. If a State requirement could be considered to relate to State licensing simply because the State could revoke a health plan's license for a failure to meet the requirement, this would mean that States could impose virtually any requirement they wished to impose without the requirement being preempted. ... Because we believe that it is clear that the Congress intended to broaden the scope of Federal preemption, not to narrow it, we also believe that the exception for laws relating to State licensing must be limited to requirements for becoming State licensed (such as filing articles of incorporation with the appropriate State agency, or satisfying State governance requirements), and not extended to rules that apply to State licensed health plans. (69 FR 46904.)

We are adopting these preemption interpretations as our final policy. We also note that in the accompanying regulation text we have replaced PDP sponsor with Part D sponsor, as we believe that the preemption of State law and the prohibition against imposition of premium taxes should operate uniformly for all Part D sponsors. We note that licensure requirements in this Part continue to apply only to PDP sponsors, as other Part D sponsors (such as MA organizations and cost-based HMOs and CMPs) are subject to their own licensing laws.

Comment: One large insurer felt that our narrow interpretation of the statutory preemption authority was contrary to the language of section 1856(b)(3) of the Act. This insurer requested that CMS consider making clear that all State laws and regulations (with the exception of State licensing and solvency laws) are preempted with respect to MA and Part D plans.

Response: As noted in the proposed rule, we do not believe that either the

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(4) Prohibition of midyear implementation of significant new regulatory requirements

The Secretary may not implement, other than at the beginning of a calendar year, regulations under this section that impose new, significant regulatory requirements on a Medicare + Choice organization or plan.

(Aug. 14, 1935, c. 531, Title XVIII, § 1856, as added Aug. 5, 1997, Pub.L. 105–33, Title IV, § 4001, 111 Stat. 317, and amended Dec. 21, 2000, Pub.L. 106–554, § 1(a)(6) [Title VI, § 612(a), 614(a)], 114 Stat. 2763, 2763A–560; Dec. 8, 2003, Pub.L. 108–173, Title II, § 232(a), 117 Stat. 2208.)

HISTORICAL AND STATUTORY NOTES

Revision Notes and Legislative Reports

2003 Acts. House Conference Report No. 108–391 and Statement by President, see 2003 U.S. Code Cong. and Adm. News, p. 1808.

Amendments

2003 Amendments. Subsec. (b)(3). Pub.L. 108–173, § 232(a), rewrote par. (3), which formerly read:

"(A) In general

"The standards established under this subsection shall supersede any State law or regulation (including standards described in subparagraph (B)) with respect to Medicare + Choice plans which are offered by Medicare + Choice organizations under this part to the extent such law or regulation is inconsistent with such standards.

"(B) Standards specifically superseded

"State standards relating to the following are superseded under this paragraph:

"(i) Benefit requirements (including cost-sharing requirements).

"(ii) Requirements relating to inclusion or treatment of providers.

"(iii) Coverage determinations (including related appeals and grievance processes).

"(iv) Requirements relating to marketing materials and summaries and schedules of benefits regarding a Medicare + Choice plan."

Effective and Applicability Provisions

2003 Acts. The amendments made by Pub.L. 108–173, § 232, shall take effect Dec. 8, 2003, see Pub.L. 108–173, § 232(c), set out as a note under 42 U.S.C.A. § 1395w–24.

Implementation of Medicare Advantage Program

Reference to program under this part deemed reference to the Medicare Advantage program, reference to "Medicare + Choice" deemed a reference to "Medicare Advantage" and "MA", and Secretary to provide for transition in the use of the such terms, to be fully completed for all materials for plan years beginning not later than January 1, 2006, see Pub.L. 108–173, § 201, set out as a note under 42 U.S.C.A. § 1395w–21.

LIBRARY REFERENCES

American Digest System

Health ⇐533.
Insurance ⇐2453.
Key Number System Topic Nos. 198H, 217.

Research References

Encyclopedias

Am. Jur. 2d Social Security and Medicare § 2373, Overview of Plan Benefits..

§ 1395w–27. Contracts with Medicare + Choice organizations

(a) In general

The Secretary shall not permit the election under section 1395w–21 of this title of a Medicare + Choice plan offered by a Medicare + Choice organization under this part, and no payment shall be made under section 1395w–23 of this title to an organization, unless the Secretary has entered into a contract under this section with the organization with respect to the offering of such plan. Such a contract with an organization may cover more than 1 Medicare + Choice plan. Such contract shall provide that the organization agrees to comply with the applicable requirements and standards of this part and the terms and conditions of payment as provided for in this part.

(b) Minimum enrollment requirements

(1) In general

Subject to paragraph (2), the Secretary may not enter into a contract under this section with a Medicare + Choice organization unless the organization has—

(A) at least 5,000 individuals (or 1,500 individuals in the case of an organization that is a provider-sponsored organization) who are receiving health benefits through the organization, or